K080771

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c)

Submitter's Name And Address:	Top Corporation 19-10 Senju Nakai-cho Adachi-ku Tokyo, Japan 120-0035
Contact Name:	Toshimitsu Suzuki
Tel.	+81 3-3882-3101
Submission Date:	December 12, 2007

NOV 10 2008

Device

Trade or (Proprietary) Name:	Top Neuropole Needles
Common or usual name:	Pole Needles
Classification Name:	Probe, radiofrequency lesion Class II devices. (21 C.F.R. § 882.4725)
Product Code:	GXI
Legally Marketed Device To Which Claim Substantial Equivalence:	Radionics: K870028, K980430, K010202 Top: K062946 Cosman: K060799

DEVICE DESCRIPTION

Top Neuropole Needles are injection needles which are used for temperature controlled radiofrequency lesioning. A nerve is localized either by using electrical stimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. After injection of anesthetics the nerve may then be blocked by radiofrequency lesion. Top Neuropole Needles are supplied sterile and are labeled for Single Use Only.

INTENDED USE

The Top Neuropole Needles are injection needles which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

TECHNOLOGICAL CHARACTERISTICS

Top Neuropole Needles have the same device characteristics, materials, dimensions and intended use as the predicate device(s).

Top Neuropole Needles have been tested to ensure the devices comply with applicable industry standards and US regulations

CONCLUSIONS

The intended use and performance characteristics of the Top Neuropole Needles are the same as the predicate(s) and raise no new questions of safety and effectiveness. The Top Neuropole Needles are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Top Corporation
% Cambria Regulatory Consulting, Inc.
Ms. Cathryn N. Cambria
5536 Trowbridge Drive
Dunwoody, Georgia 30338

NOV 10 2008

Re: K080771
Trade/Device Name: Top Neuropole Needles, Model SII, BL, SC & TC
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI
Dated: October 16, 2008
Received: October 20, 2008

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080771

Indications for Use:

510(k) Number (if known): K080771

Device Name: Top Neuropole Needles, Model SH, BL, SC & TC

Indications for Use:

The Top Neuropole Needles are injection needles which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080771